In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 28, 2024

BASIL MCNEELY,	*	
	*	Special Master Sanders
Petitioner,	*	
v.	*	No. 18-1243V
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Renee J. Gentry, The Law Office of Renee J. Gentry, Washington, DC, for Petitioner.
Jamica M. Littles, United States Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On August 20, 2018, Basil McNeely ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner later filed an amended petition on October 14, 2020. Petitioner alleged that the administration of the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine he received on August 21, 2016 caused significant aggravation of his preexisting cervical radiculopathy.[3] Am. Pet. at 2, ECF No. 48.

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards,[4] I find that Petitioner has met his legal burden.

[1]Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act," "the Act," or "the Program"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] Cervical radiculopathy is "radiculopathy of cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." *Dorland's Illustrated Medical Dictionary* at 1547 (33rd ed. 2020) [hereinafter "*Dorlands*"].

[4] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328

Petitioner has provided preponderant evidence that the Tdap vaccine he received on August 21, 2016, caused significant aggravation of his cervical radiculopathy. Accordingly, Petitioner is entitled to compensation.

I. Procedural History

The original petition filed on August 20, 2018, alleged that Petitioner suffered from a shoulder injury related to vaccine administration ("SIRVA") as a result of a Tdap vaccination. Pet. at 1, ECF No. 1. This case was assigned to the Special Processing Unit ("SPU"). ECF Nos. 4–5. Petitioner filed sixteen exhibits on August 22, 2018, including vaccination and medical records. *See* Petitioner's Exhibits ("Pet'r's Exs.") 1–17, ECF Nos. 6–7. On October 29, 2018, Petitioner filed additional medical records and a statement of completion. Pet'r's Exs. 18–38, ECF Nos. 9–12. An initial status conference was held on December 11, 2018. Min. Entry, docketed Dec. 13, 2018. Petitioner filed additional medical records and a second statement of completion on January 11, 2019. Pet'r's Ex. 39, ECF No. 20-2; ECF No. 21. Petitioner filed an affidavit on August 21, 2019, and additional medical records on September 17, 2019. Pet'r's Exs. 40–49, ECF Nos. 28–29. On September 19, 2019, Petitioner filed a third statement of completion. ECF No. 30. Petitioner filed additional exhibits on September 23, 2019. Pet'r's Exs. 50–51, ECF No. 32. On October 16, 2019, Petitioner filed a consented motion to substitute his attorney, which was granted the next day. ECF No. 33.

On January 21, 2020, Respondent filed a Rule 4(c) Report in which he recommended against compensating Petitioner for his alleged injury. *See* Respondent's Report ("Resp't's Report"), ECF No. 37. Respondent averred that Petitioner had not established that he suffered from a Table SIRVA. *Id.* at 10–16. Alternatively, Petitioner alleges that the vaccine was the cause-in-fact of his shoulder injury. *Id.*

On March 30, 2020, Petitioner filed an additional exhibit, a spreadsheet of past expenses. Pet'r's Ex. 52, ECF No. 39-1. On April 2, 2020, Respondent indicated that he was not interested in pursuing settlement, and the case was reassigned to me on April 3, 2020. ECF Nos. 40–42.

Petitioner filed an expert report from Carlo Tornatore, M.D., accompanied by a curriculum vitae ("CV") and medical literature on October 12, 2020. Pet'r's Ex. 53–56, ECF No. 47. Two days later, Petitioner filed his amended petition, which alleged that the Tdap vaccine caused significant aggravation of Petitioner's preexisting cervical radiculopathy, rather than the previously pled SIRVA. *See* Am. Pet. at 2. Petitioner filed insurance claim documents on December 17, 2020. Pet'r's Ex. 57-2, ECF No. 49. Respondent filed an expert report authored by Brian C. Callaghan, M.D., M.S, along with Dr. Callaghan's CV and medical literature on February 19, 2021. Resp't's Exs. A–B, ECF No. 51. On May 24, 2021, Petitioner filed a responsive expert report from Dr. Tornatore with medical literature. Pet'r's Exs. 58–59, ECF No. 55. Respondent filed a responsive expert report from Dr. Callaghan on August 9, 2021. Resp't's Ex. C, ECF No. 56-1.

(Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

On November 9, 2022, the parties indicated via email that they would like to proceed with a ruling on the record. Informal Comm., docketed Nov. 9, 2022. Petitioner filed a motion for a ruling on the record on December 12, 2022. Pet'r's Mot., ECF No. 61. Respondent filed a response on January 9, 2023. Resp't's Resp., ECF. No. 62. Petitioner filed a reply on January 25, 2023. Pet'r's Reply, ECF No. 63. This matter is now ripe for consideration.

II. Summary of the Relevant Evidence

a. Medical Records

i. Pre-Vaccination History

Petitioner was 60 years old at the time of vaccination and his past medical history is significant for lumbar disc disease,[5] chronic headaches, low back pain, and mitral valve prolapse.[6] Pet'r's Ex. 23 at 14, ECF No. 9-7. On June 3, 2013, Petitioner saw rheumatologist Dr. Thomas McGee at the IMC Diagnostic & Medical Clinic for pain in his upper left arm, which seemed to "radiat[e] from his neck into his arm." Pet'r's Ex. 43 at 10–11, ECF No. 29-4. Petitioner also noted "a little weakness in the left arm" and cramps in his feet and arms at times. *Id.* at 10. Petitioner further reported "prior problems with his neck in the past." *Id.* Upon physical examination, Dr. McGee found "[Petitioner] does definitely have radicular pain in his left arm. He has a significantly reduced biceps reflex on the left and triceps reflex on the left, normal on the right." *Id.* Dr. McGee further noted that Petitioner's shoulders, elbows, and wrists were "okay" and that Petitioner had "free range of the motion of [his] left shoulder." *Id.* Dr. McGee diagnosed Petitioner with cervical radiculopathy and lumbar disc disease. *Id.* Dr. McGee gave Petitioner an injection of "1-1/2 cc of Kenalog,"[7] a soft cervical collar, and a neck protocol to follow at home. *Id.* at 11. Petitioner was advised to consider physical therapy and call if he did not feel better. *Id.* That same day, Petitioner

[5] Lumbar disc disease is "caused by a change in the structure of the normal disk. Most of the time, disk disease happens as a result of aging and the normal breakdown that occurs within the disk. Sometimes, severe injury can cause a normal disk to herniate. Injury may also cause an already herniated disk to worsen." *Johns Hopkins Medicine* (Apr. 24, 2024, 4:00pm), https://www.hopkinsmedicine.org/health/conditions-and-diseases/lumbar-disc-disease-herniated-disc#:~:text=Lumbar%20disk%20disease%20is%20caused,already%20herniated%20disk%20to%20worsen. Symptoms "vary depending on where the disk has herniated and what nerve root it is pushing on" but can commonly include intermittent or continuous back pain, spasm of the back muscles, sciatica, muscle weakness in the legs, numbness in the leg or foot, and decreased reflexes at the knee or ankle. *Id.*

[6] Mitral valve prolapse is "redundancy or hooding of mitral valve leaflets so that they prolapse into the left atrium, often causing mitral regurgitation." *Dorlands* at 1502.

[7] Kenalog is a "trademark for preparations of triamcinolone acetonide" which is "applied topically to the skin or oral mucosa as an antiinflammatory, and administered by inhalation for the chronic treatment of asthma, intranasally in the treatment of allergic rhinitis and other inflammatory nasal conditions, and by intra-articular, intradermal, intralesional, intramuscular, intrabursal, or tendon sheath injection as an antiinflammatory and immunosuppressant in a wide variety of disorders." *Dorlands* at 966,1929.

underwent a left shoulder x-ray which revealed normal acromioclavicular[8] and glenohumeral[9] joints and no acute fracture or dislocation. *Id.* at 15. Petitioner also underwent a cervical spine series x-ray, which revealed "[d]egenerative appearing changes worse at C5-C6 but some spurring[10] is seen at C6-C7 with mild neural foraminal narrowing[11] worse on the left than right." *Id.* at 16.

In August 2013, Petitioner underwent a two-night sleep study at Springhill Medical Center. Pet'r's Ex. 36 at 10, ECF No. 11-2. A review of systems included arthralgias,[12] back pain, muscle weakness, and neck pain. *Id.* Dr. Lawrence Schoen diagnosed Petitioner with "obstructive sleep apnea[13] characterized by hypopneas"[14] and "periodic limb movement disorder."[15] *Id.* at 15. Petitioner was given instructions for a trial continuous positive airway pressure[16] ("CPAP") machine at home. *Id.* at 18.

Between January 2014 and February 2016, Petitioner visited the University of South Alabama Speech Pathology and Audiology clinic for sinus-related issues, specifically when using his CPAP machine. Pet'r's Ex. 35 at 11–14, ECF No. 10-10. Each visit, Petitioner was prescribed various antibiotics and given steroid "injections of 8 [mg of Decadron[17]] and 160 [mg of Depo-Medrol[18]]." *Id.* at 14, 16.

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[8] The acromioclavicular joint is "the synovial joint between the acromion of the scapula and the acromial extremity of the clavicle." *Dorlands* at 20, 959.

[9] The glenohumeral joint is "the joint formed by the head of the humerus and the glenoid fossa of the scapula" and also called the "shoulder." *Dorlands* at 960.

[10] A spur is "a projecting body, as from a bone." *Dorlands.* At 1728.

[11] Neural foraminal narrowing, also known as spinal stenosis, is "narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration." *Dorlands* at 1740.

[12] Arthralgia is "pain in a joint." *Dorlands* at 154.

[13] Sleep apnea syndrome is "transient periods of cessation of breathing during sleep. It may result in hypoxemia and vasoconstriction of pulmonary arterioles, producing pulmonary arterial hypertension." *Dorlands* at PAGE 1818.

[14] Hypopnea is an "abnormal decrease in the depth and rate of breathing." *Dorlands* at 893.

[15] Periodic limb movement disorder, also called nocturnal myoclonus, is "myoclonic jerks of the limbs occurring as a person is falling asleep or is asleep; in the latter case they may disrupt sleep." *Dorlands* at 546, 1205.

[16] Continuous positive airway pressure, or CPAP, is "a method of positive pressure ventilation used with patients who are breathing spontaneously, in which pressure in the airway is maintained above the level of atmospheric pressure throughout the respiratory cycle. The purpose is to keep the alveoli open at the end of exhalation and thus increase oxygenation and reduce the work of breathing." *Dorlands* at 422.

[17] Decadron is a trademark name for "preparations of dexamethasone." *Dorlands* at 468. Dexamethasone is "a synthetic glucocorticoid, 25 times as potent as cortisol; used topically on the skin and conjunctiva as an antiinflammatory and administered orally in replacement therapy for adrenocortical insufficiency, as an antiinflammatory and immunosuppressant in a wide variety of disorders, and as an antiemetic in cancer chemotherapy." *Id.* at 497.

[18] Depo-Medrol is a trademark name for "preparations of methylprednisolone acetate." *Dorlands* at 486. Methylprednisolone acetate is "the 21-acetate ester of methylprednisolone, administered topically as an antiinflammatory, by intramuscular injection in replacement therapy for adrenocortical insufficiency, and

Between October 2014 and January 2016, Petitioner visited The Autonomic Disorders and Mitral Valve Prolapse Center three times for follow-up appointments for his mitral valve prolapse. Pet'r's Ex. 20 at 3–5, ECF No. 9-4.

ii. Post -Vaccination Medical History

On August 21, 2016, Petitioner received a Tdap vaccine in his left shoulder at a Walmart pharmacy in Mobile, Alabama. Pet'r's Ex. 39 at 10–11. Five days later, on August 26, 2016, Petitioner saw Dr. John Hinton, a neurologist and Petitioner's longtime friend, for "trouble thinking and concentrating." Pet'r's Ex. 23 at 14. Petitioner noted that he "had these kind of problems in the past" and they improved with amphetamines and CPAP. *Id.* Petitioner reported "spells of 'spacing out[,]' where he has a buzzing feeling between his eyes" which was worse in the afternoon. *Id.* Petitioner also reported weight gain since he could not exercise due to back pain and the inability to tolerate stimulants. *Id.* Petitioner also noted that he was compliant with CPAP. *Id.* The review of systems was notable for malaise/fatigue, blurred vision, back pain, tingling, headaches, nervousness/anxiety, and insomnia. *Id.* The physical exam showed full motor strength in all extremities and normal tone. *Id.* Dr. Hinton's primary diagnosis was obstructive sleep apnea syndrome, with additional diagnoses of attention deficit disorder, memory loss, and hypersomnia[19] with sleep apnea. *Id.* at 16. Dr. Hinton's treatment plan included imaging and labs, a Zoloft[20] prescription, weight loss, and a regular, graduated exercise program. *Id.*

Eighteen days post vaccination, on September 8, 2016, Petitioner returned to Dr. McGee complaining "of a reaction to [Tdap]." Pet'r's Ex. 43 at 7. Dr. McGee noted that Petitioner "complain[ed] of left arm pain that 'feels like there's a spear stuck in,' sa[id] that it hurt[] all the way down to his left hand." *Id.* Petitioner reported a history of a pinched nerve in his neck and noted some stiffness in his neck, exacerbated by certain positions. *Id.* Dr. McGee's physical examination of the left shoulder showed "no swelling, no warmth, no tenderness to touch[]" as well as "[a] little atrophy to deltoid." *Id.* at 9. During the exam, Petitioner also "[c]omplain[ed] of pain with [range of motion] of neck." *Id.* Petitioner was diagnosed with cervical radiculopathy and lumbar disc disease. *Id.* Dr. McGee noted that Petitioner's arm pain was a "[r]eaction to [Tdap]. Possibly referred pain from neck, no induration." *Id.* Dr. McGee prescribed 200mg of Celebrex[21] for the pain. *Id.* He also prescribed 2 mg of Zanaflex,[22] a muscle relaxant, for Petitioner's lumbar disc disease. *Id.* Petitioner was advised to follow up in six months, or earlier if needed. *Id.*

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by intra-articular, intramuscular, intralesional, or soft-tissue injection as an antiinflammatory and immunosuppressant in a wide variety of disorders." *Id.* at 1137.

[19] Hypersomnia is "excessive sleeping or sleepiness." *Dorlands* at 885.

[20] Zoloft is a trademark name for "preparations of sertraline hydrochloride." *Dorlands* at 2061. Sertraline hydrochloride is "a selective serotonin reuptake inhibitor, used to treat depressive, obsessive-compulsive, and panic disorders; administered orally." *Id.* ay 1671.

[21] Celebrex is a trademark name "for a preparation of celecoxib." *Dorlands* at 307. Celecoxib is "a nonsteroidal antiinflammatory drug of the COX-2 inhibitors group, used for symptomatic treatment of osteoarthritis and rheumatoid arthritis; administered orally." *Id.*

[22] Zanaflex is a trademark name for a "preparation of tizanidine hydrochloride." *Dorlands* at 2060. Tizanidine hydrochloride is "an α2-adrenergic agonist used as a short-acting agent to manage the increased muscle tone associated with spasticity, as that related to multiple sclerosis or spinal cord injury; administered orally." *Id.* at 1903.

On September 11, 2016, Petitioner presented to Greater Mobile Urgent Care for complaints of left arm pain and muscle spasms of the left upper back. Pet'r's Ex. 2 at 6–10, ECF No. 6-3. Petitioner reported that the Celebrex and muscle relaxer were not working. *Id.* at 7. The clinical impression was "left shoulder pain/left upper arm pain, muscle spasm left upper back." *Id.* at 6. Petitioner received a Kenalog injection and was advised to follow up with Dr. McGee if he did not feel better. *Id.*

On September 21, 2016, Petitioner reported to his chiropractor, Dr. Gregory Kuhlman, at Family Chiropractic and Health Center, P.C. Pet'r's Ex. 4 at 4, ECF No. 6-5. Petitioner reported "constant severe pain in the neck" and an "insidious onset about a month ago of moderately severe numb sensations and tingling sensations radiating to the left arm, left forearm and left hand." *Id.* Petitioner also noted that his symptoms began after receiving a vaccine in his left arm and that there was "constant moderately severe stiffness in his neck and left shoulder along with some weakness in his left hand." *Id.* Dr. Kuhlman diagnosed Petitioner with cervicalgia,[23] spasm of muscle, cervicobrachial syndrome[24] (diffuse), and pain in joint involving shoulder region. *Id.* Petitioner received ice therapy to the cervical spine, interferential therapy[25] in the cervical spine and upper thoracic spine, and neck adjustment. *Id.* Dr. Kuhlman instructed Petitioner to use ice at home. *Id.*

The next day, on September 22, 2016, Petitioner followed up with neurologist Dr. Hinton for "pain down left arm to thumb" which "started with [Tdap] shot." Pet'r's Ex. 23 at 11. Petitioner reported that the pain was better following chiropractic treatment but was "now worse again." *Id.* Dr. Hinton diagnosed Petitioner with cervical radiculopathy at C6, memory loss, obstructive sleep apnea syndrome, attention deficit disorder, and hypersomnia with sleep apnea. *Id.* at 13. Petitioner was prescribed a steroid, Medrol,[26] and imaging was ordered. *Id.* Weight loss and a regular exercise program were encouraged. *Id.* That same day, an MRI of the cervical spine found spondylosis[27] at C5-6 and C6-7 with bilateral foraminal stenosis.[28] Pet'r's Ex. 6 at 6–7, ECF No. 6-7. This imaging was limited to only T2 sagittal sequences because Petitioner was in pain and could not complete the full session. *Id.* at 7.

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[23] Cervicalgia is "neck pain." *Cleveland Clinic* (Apr. 24, 2024, 4:32pm), https://my.clevelandclinic.org/health/symptoms/21179-neck-pain.

[24] Cervicobrachial syndrome, also known as brachial plexopathy, is "any neuropathy of the brachial plexus." *Dorlands* at 1440, 1794.

[25] Interferential therapy is a therapy that utilizes "the production of low frequency current in the body tissue by the simultaneous application of two different medium frequency currents." *Physiopedia* (Apr. 24, 2024, 4:38pm), https://www.physio-pedia.com/Interferential_Therapy.

[26] Medrol is a trademark name "for preparations of methylprednisolone." *Dorlands* at 1105. Methylprednisolone is "a synthetic glucocorticoid derived from progesterone, used in replacement therapy for adrenocortical insufficiency and as an antiinflammatory and immunosuppressant in a wide variety of disorders; administered orally." *Id.* at 1137.

[27] Spondylosis is "1. ankylosis of a vertebral joint. 2. degenerative spinal changes due to osteoarthritis." *Dorlands* at 1725.

[28] Foraminal stenosis "is a condition that happens when narrowing in parts of your spine causes compression of your spinal nerves. Most cases don't cause symptoms, even with severe narrowing. However, when there are symptoms, pain and nerve-related issues can happen." *Cleveland Clinic* (Apr. 24, 2024, 4:43pm), https://my.clevelandclinic.org/health/diseases/24856-foraminal-stenosis.

Petitioner underwent an electromyogram and nerve conduction study ("EMG/NCS") on September 30, 2016. Pet'r's Ex. 10 at 31–32, ECF No. 7-2. The study revealed "[l]eft C7 radiculopathy" and normal bilateral upper extremities. *Id.* at 32.

On September 30, 2016, Petitioner returned to Dr. Hinton for a follow-up. Pet'r's Ex. 23 at 8–10. Dr. Hinton noted that Petitioner's EMG/NCS revealed C7 radiculopathy. *Id.* at 8. Dr. Hinton also noted that Petitioner "[h]ad trouble tolerating MRI" and that the Medrol helped with his pain. *Id.* Dr. Hinton diagnosed Petitioner with neck and cervical radicular pain. *Id.* at 10. Further imaging was recommended, along with continued weight loss and exercise. *Id.* Petitioner returned for a follow-up for neck pain on October 21, 2016, this time seeing nurse practitioner Tami Dunne. *Id.* at 5. Petitioner also complained of migraines and reported numbness and weakness in his left arm. *Id.* Petitioner received refills for Zanaflex, Tenormin,[29] and Mobic,[30] and was encouraged to lose weight and exercise. *Id.* at 7.

Petitioner saw Dr. Khulman for chiropractic treatment on October 3, 2016, October 5, 2016, October 7, 2016, and October 14, 2016. Pet'r's Ex. 4 at 10–13. The treatments included inferential therapy to the neck, cervical spine, and upper thoracic areas, cryotherapy,[31] chiropractic adjustment to the neck and spine, ice and cold therapy to the cervical spine, deep muscle massage, and trigger point therapy. *Id.*

On January 23, 2017, Petitioner saw Dr. Paula Moore at the Dysautonomia MVP Center for complaints of tachycardia,[32] sleep apnea, hyperlipidemia, shortness of breath, depression, and migraines. Pet'r's Ex. 20 at 6. The history of present illness states that Petitioner "had a [Tdap] immunization back in August and he suddenly developed pain in his arm where he received the immunization." *Id.* Petitioner reported that he had seen a neurologist, had undergone a nerve conduction study, and had received a diagnosis of peripheral neuropathy.[33] *Id.* Petitioner also noted that he had been on gabapentin[34] and it had helped, though he still had some pain in the left arm "but it [was] much better." *Id.* Petitioner further complained of a mild and non-exertional tightness in his chest on a fairly regular basis, and he attributed this to the immunization as well. *Id.* Additionally, Petitioner reported experiencing tachycardia and shortness of breath when he was exerting, which was usually relieved with rest. *Id.* A physical exam showed normal muscle tone, strength, and motor and sensory functions. *Id.* Dr. Moore diagnosed Petitioner with shortness of breath, tachycardia, obstructive sleep apnea, polyneuropathy, and obesity. *Id.* at 7. Dr. Moore also

[29] Tenormin is a trademark name "for preparations of atenolol." *Dorlands* at 1853. Atenolol is "a cardioselective β1-adrenergic blocking agent used in the treatment of hypertension and chronic angina pectoris and the prophylaxis and treatment of myocardial infarction and cardiac arrhythmias; administered orally or intravenously." *Id.* at 169.

[30] Mobic is a trademark name for "a preparation of meloxicam." *Dorlands* at 1154. Meloxicam is "a nonsteroidal antiinflammatory drug used in the treatment of osteoarthritis; administered orally." *Id.* at 1111.

[31] Cryotherapy is "the therapeutic use of cold." *Dorlands* at 433.

[32] Tachycardia is "excessive rapidity in the action of the heart." *Dorland's* at 1836.

[33] Peripheral neuropathy, also known as poly neuropathy, is "neuropathy of several peripheral nerves simultaneously." *Dorland's* at 1252, 1468.

[34] Gabapentin is "an anticonvulsant that is a structural analogue of γ-aminobutyric acid (GABA), used as adjunctive therapy in the treatment of partial seizures and the management of postherpetic neuralgia; administered orally." *Dorland's* at 745.

ordered an electrocardiogram ("EKG") for Petitioner's shortness of breath and counseled Petitioner on exercise. *Id.*

Petitioner presented to Dr. William Trent at the Mobile Infirmary Medical Center for a cervical epidural steroid injection[35] on July 14, 2017. Pet'r's Ex. 5 at 49, ECF No. 6-6. The diagnosis was cervical radiculitis which resulted in "pain not controlled by other means." *Id.* The injection of Depo-Medrol was inserted at the C6-7 level. *Id.*

On January 15, 2018, Petitioner returned to Dr. Moore for a follow-up visit regarding fatigue, weight gain, palpitations, and tachycardia. Pet'r's Ex. 20 at 9. Petitioner reported that he was no longer taking gabapentin for nerve damage in his arms because it "was not working well for him." *Id.* Petitioner "continue[ed] to have paresthesias[36] and soreness in his left arm, as well as some issues with his right hand." *Id.* Petitioner also reported the most relief with epidural block treatments. *Id.*

Petitioner saw neurosurgeon Dr. Troy Middleton at the Coastal Neurological Institute on February 19, 2018, for an initial evaluation of neck, arm, and shoulder pain. Pet'r's Ex. 3 at 5, ECF No. 6-4. Petitioner specifically reported that he experienced numbness in his hands and arms, with the left side being worse. *Id.* Petitioner reported that his past treatment included steroids, epidural injections, and chiropractor treatment. *Id.* The review of systems showed muscle cramps, joint and back pain, muscle weakness and aching, loss of strength, poor balance, disturbances in coordination, numbness, and tingling. *Id.* at 6. Dr. Middleton diagnosed Petitioner with cervicalgia and recommended imaging. *Id.* at 7. On February 28, 2018, Petitioner had a follow-up to review the results of his MRI, which revealed moderate spondylosis at C5-7 with foraminal stenosis. *Id.* at 9–12.

On May 8, 2018, Petitioner presented to orthopedist Dr. Stephen Cope at The Orthopedic Group for "left arm pain." Pet'r's Ex. 10 at 9. Petitioner reported that he had a shot in his left shoulder in August of 2016 and experienced significant pain that had worsened with time. *Id.* Petitioner described his left arm as "somewhat weak." *Id.* Petitioner listed the various treatments he had sought to no avail. *Id.* Dr. Cope informed Petitioner that he would like to review the records from Dr. Hinton and Dr. Middleton and advised that he might refer Petitioner to a spine surgeon for an opinion. *Id.* at 10. Petitioner returned on May 14, 2018 and saw Dr. Clinton Howard. *Id.* at 7. Dr. Howard's assessment was "left upper extremity weakness in grip as well as elbow flexion and extension with MRI showing moderate stenosis of the cervical spine without significant cervical neck pain." *Id.* Petitioner was referred to physical therapy and given a Medrol Dosepak. *Id.*

Petitioner began physical therapy at Hall Therapy Services on May 17, 2018. Pet'r's Ex. 8 at 55, ECF No. 6-9. The assessment included "painful motion, decreased [range of motion],

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[35] Cervical epidural steroid injection is used "as a temporary pain relief option for certain causes of chronic neck pain" and issued as an injection of "anti-inflammatory medication into the epidural space around [the] spinal nerves." *Cleveland Clinic* (Apr. 24, 2024 at 4:54pm), https://my.clevelandclinic.org/health/treatments/22293-cervical-epidural-steroid-injection.

[36] Paresthesia is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." *Dorland's* at 1362.

weakness, muscle tightness, radicular symptoms, spasm, and decreased postural awareness that is limiting his daily function." *Id.* at 57. The plan included physical therapy two to three times a week for four weeks. *Id.* at 58. By Petitioner's last physical therapy session on June 18, 2018, the assessment stated:

> [I]mproved [range of motion] of the cervical spine and shoulder as increased strength in the C spine. [Petitioner] feels his quality of life has improved due to better [range of motion] but he does not feel he has had any change of pain in the shoulder/[upper extremity]. [Petitioner] reports absolutely no change in pain/discomfort in the [upper extremity] and it still hurts to touch but the pain is no longer considered constant. Goals have been addressed but have not been met.

Id. at 9. Petitioner was advised to follow up with his doctor for further recommendations. *Id.*

On July 22, 2019, Petitioner had a yearly appointment with nurse practitioner Meleah Yates at the Dysautonomia MVP Center. Pet'r's Ex. 46 at 8, ECF No. 29-7. Petitioner reported that he was still experiencing numbness, tingling, and pain in his left arm since his vaccination. *Id.* at 9. Petitioner also noted that "the pain . . . [was] tolerable without med[ication]." *Id.* Ms. Yates noted that the vaccination "was administered in the wrong place and [Petitioner] has had trouble since then." *Id.* Ms. Yates also recorded that Petitioner has completed physical therapy. *Id.*

b. Petitioner's Affidavit

Petitioner filed an affidavit, which was executed on July 26, 2019. Pet'r's Ex. 40 at 7, ECF No. 28-2. Petitioner recalled that he was planning to get the Tdap vaccination in preparation for the birth of a grandchild. *Id.* ¶ 1. Petitioner recalled shopping at Walmart on August 21, 2016 when he noticed that the pharmacy offered vaccinations, and he signed up to receive his Tdap vaccination. *Id.* ¶ 2. Petitioner stated that the administering professional "began by putting some sort of bandage in place on [Petitioner's] left arm before giving the injection." *Id.* ¶ 3. When Petitioner questioned "putting the needle through a bandage," the administering professional stated, "[t]his is the way we do it at Walmart to protect you from germs in the store." *Id.* Petitioner recalled that the vaccination "hurt a lot more than other vaccinations [he] ha[d] taken. Tetanus shots do hurt, but this REALLY hurt as [he] walked out of the store." *Id.* Petitioner further recalled returning home, laying down, and resting because he "did not feel like doing anything with [his] arm so uncomfortable." *Id.* ¶ 4. Petitioner stated that by the next morning, his "left arm was extremely painful." *Id.* Petitioner recalled that he took some ibuprofen and attempted exercising the arm, "hoping to work the discomfort out." *Id.*

Over the course of the next week, Petitioner recalled having "tense and hard" shoulder muscles such that "it was difficult to work or rest." *Id.* ¶ 5. Petitioner stated that "it did not get better with time like a shot usually does[.]" *Id.* On August 28, 2017, Petitioner and his wife returned to Walmart to advise of the problem because he "did not want it to happen to others, especially young children, and [he] thought the shot was given wrong somehow." *Id.* The store manager spoke to the pharmacy staff and determined that the administrating professional was a "trainee from another store." *Id.* The store manager "then apologized." *Id.* That day, Petitioner

bought topical medicines and pain patches, but "the pain seemed to spread down [his] arm and into [his] shoulder and side." *Id.* ¶ 6.

Petitioner recalled that, on September 8, 2016, he saw his internist, Dr. McGee, who gave him "a muscle relaxer and Celebrex." *Id.* Petitioner attended an appointment at Massage Envy on September 9, 2016, based off the recommendation of a coworker. *Id.* ¶ 7. Petitioner added that "[t]he massage was difficult for [him], as [he] had to keep putting the arm in different positions as it stiffened," but that he received "some relief" from the massage that day. *Id.* However, Petitioner stated that the relief "did not last very long" and that he felt stiff by the next morning. *Id.*

By September 10, 2016, Petitioner stated that he was in "too much pain to lay down or sleep[,]" and he visited an urgent care the next day to "try a corticosteroid shot, hoping for some relief." *Id.* ¶ 8. Petitioner received the injection in his hip, but "it did not make much difference." *Id.* Petitioner added that he could not sleep, or lay down, on both days because of the intensity of the pain. *Id.* By September 12, 2016, Petitioner was "still sore and stiff, and only able to rest by leaning against a pile of pillows after using the shower massage[,]" and he called Dr. Hinton, his neurologist. *Id.* ¶ 9. Petitioner stated that Dr. Hinton doubled his Celebrex dosage on September 14, 2016. *Id.* Petitioned recalled calling Dr. McGee at night "describing pain and difficulty walking any distance[.]" *Id.* ¶ 10. Petitioner was advised to stop the muscle relaxer and to wear a cervical collar when driving, but this did not bring any relief. *Id.*

Petitioner stated that he saw Dr. Kuhlman at Family Chiropractic on September 21, 2016, based on a friend's recommendation. *Id.* ¶ 11. Petitioner recalled that he had to stop and stretch twice during the twenty-minute drive to the office because he was in so much pain. *Id.* During the appointment, Petitioner received nerve stimulation and adjustment, as well as the recommendation to see a neurologist to prescribe a Medrol pack. *Id.* The next day, Petitioner saw Dr. Hinton and received the Medrol prescription which "helped more than anything else had[.]" *Id.* ¶ 12. Petitioner recalled "some relief" from four visits to Dr. Kuhlman in September 2016, but that "it was short lived." *Id.* Petitioner stated that his wife "massaged [his] arm and shoulder with an electric back massager (20-30 minutes each session), so that [he] would have enough relief from the pain to go to work and so [he] could sleep at night." *Id.*

Petitioner's granddaughter was born on September 25, 2016, and Petitioner recalled that he could not travel to Texas to see her as "he could barely make the fifteen-minute commute to downtown to work, so . . . [it] was out of the question." *Id.* ¶ 13. Further, "[i]t was a heartbreak because that was the reason for [Petitioner] to get the shot in the first place. [He] was sad, mad, disappointed, broken hearted[,] and sore." *Id.*

Petitioner recalled a visit to Dr. Hinton on September 30, 2016 for a nerve test that was "intensely uncomfortable[.]" *Id.* ¶ 14. Petitioner noted that his "left arm continued to throb at the injection area if anyone touched it" and "[t]hat pain continues to this day." *Id.* Petitioner stated that he visited the chiropractor three more times in October 2016 until Dr. Kuhlman advised "he could not do any more for [Petitioner]." *Id.* ¶ 15. Petitioner also recalled visits with Dr. Hinton on October 21, 2016, November 3, 2016, and December 22, 2016, at which point Petitioner "was taking a lot of meds to control pain, including [gabapentin], hydrocodone, [Mobic], and muscle relaxers" which brought "some relief" but also made Petitioner "sleepy, probably due to the 2400

mg dosage of [gabapentin]." *Id.* Petitioner stated that he stopped the hydrocodone "after a week because it became ineffective" and soon also stopped the muscle relaxers and meloxicam, but continued with the gabapentin because it allowed him "to work a little." *Id.* Petitioner noted that his "time at work was very difficult and ineffective." *Id.*

Petitioner was scheduled for a neck epidural on March 8, 2017, but cancelled the appointment to visit his newly born grandchild in Virginia. *Id.* ¶ 16. Petitioner noted that he had to take the train because he could not drive that distance in his condition. *Id.* Petitioner later received the neck epidural on July 14, 2017, and he indicated that it numbed his neck but "did not make [his] arm well." *Id.* ¶ 17. Petitioner received a second neck epidural on August 21, 2017 with "[n]ot much difference [] noticed, and the arm did not change." *Id.*

Petitioner noted that he has "weakness in [his] left arm when doing yard work," limiting his ability to "mow, trim, and rake." *Id.* ¶ 18. Petitioner "can do little with that arm because it gets sore and tired quickly." *Id.*

Petitioner recalled seeing Dr. Middleton, a neurosurgeon, who evaluated Petitioner's neck and past MRIs. *Id.* ¶ 19. Dr. Middleton advised Petitioner of "some narrowing" in the neck, "but not enough to worry about." *Id.* Further, Dr. Middleton did not recommend an epidural and stated that the arm pain is not consistent with a problem stemming from the neck. *Id.*

Petitioner stated that he next saw Dr. Steven Cope and Dr. Clint Howard, who recommended physical therapy. *Id.* ¶ 20. Petitioner began physical therapy where he "was stretched and pulled and did neck exercises[,]" but the "work did not give [him] the arm relief that was hoped for." *Id.* ¶ 21. Petitioner added that after "several sessions and lots of home exercises, there was no progress and the therapist had nothing new to try." *Id.* Petitioner ceased therapy and returned to Dr. Howard on June 19, 2018, who recommended a third neck epidural with Dr. Trent. *Id.* ¶ 22.

Between June and July 2018, Petitioner learned that he required surgery to remove a bladder cancer tumor. *Id.* ¶ 24. While going through pre-operation requirements, Petitioner stated that he spoke with the "head surgical nurse" and inquired about his left arm pain. *Id.* ¶ 25. Petitioner added that the nurse "asked about the location of the shot, indicating that injecting it in the wrong place could really hurt someone. She was also shocked to hear that the injection was given through the bandage . . . [and] said there was no reason for that." *Id.* Petitioner cancelled the third neck epidural because of the bladder surgery. *Id.* ¶ 26. Petitioner noted that he did not reschedule the epidural because Dr. Middleton advised against it since the risk outweighed the benefits, especially considering that it didn't help the arm pain in the past. *Id.*

Petitioner concluded the affidavit with a summary of his experience. *Id.* ¶¶ 27–29. Petitioner stated that he has "tried everything the doctors prescribed and ha[s] spent a lot of time off work trying to get well from this pain that started immediately with an injection of [the] vaccine." *Id.* ¶ 27. Petitioner added that he has incurred significant debt due to the cost of the treatments and medicines, as well as lower sales from his small business due to his pain. *Id.* Petitioner noted that the gabapentin, which helped with the pain, also caused drowsiness and weight gain to the point where Petitioner stopped taking it in December of 2017 "to be able to be

clear-headed enough to work and not lose my business." *Id.* ¶ 28. However, not taking it "leaves [him] with even more pain." *Id.* Petitioner recalled a gentle pat on the arm from his 85-year-old mother after his surgery that "brought tears to [his] eyes from the arm pain." *Id.* Petitioner remarked that "there seems to be no solution" to his arm pain. *Id.* ¶ 29.

c. Expert Review

i. Expert Backgrounds

1. Petitioner's Expert, Carlo Tornatore, M.D.

Dr. Tornatore received his medical degree from Georgetown University School of Medicine in 1986. Pet'r's Ex. 54 at 3, ECF No. 47-3. Dr. Tornatore then completed an internship in internal medicine at Providence Hospital and residency in neurology at Georgetown University Hospital. *Id.* Next, Dr. Tornatore completed a fellowship in molecular virology at the National Institutes of Health. *Id.*

Presently, Dr. Tornatore is Professor and Chairman of the Department of Neurology at Georgetown University Medical Center ("GUMC") and Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital. Pet'r's Ex. 53 at 1, ECF No. 47-2. At GUMC, Dr. Tornatore oversees "the research endeavors of 15 laboratories, consisting of 19 Principal Investigators and over 90 post-doctoral fellows, doctoral candidates, graduate students and lab technicians." *Id.* The labs focus on "various aspects of the neuroscience, including neuroplasticity, neuroimaging, cognitive neuroscience and language disorders[.]" *Id.* Dr. Tornatore also oversees over sixty clinical trials at the GUMC Department of Neurology, including fifteen of which he is the principal investigator. *Id.* At Medstar Georgetown University Hospital, Dr. Tornatore oversees the clinical endeavors of sixty-five neurologists at five hospitals. *Id.*

Dr. Tornatore also serves as the executive director of the Multiple Sclerosis ("MS") Patient Centered Specialty Home with over 3,000 patients. *Id.* In addition to MS patients, the clinic also cares for patients with various other inflammatory conditions of the brain and spinal cord and various inflammatory disorders of the peripheral nervous system. *Id.* at 2.

2. Respondent's Expert, Brian Callaghan, M.D., M.S.

Dr. Callaghan received his medical degree from the University of Pennsylvania Medical Center in 2004. Resp't's Ex. B at 1, ECF No. 51-4. Dr. Callaghan then completed an internship in preliminary medicine in 2005 and a neurology residency in 2008 at the University of Pennsylvania Medical Center. *Id.* Dr. Callaghan also completed two fellowships, the first in 2009 with a neuromuscular focus at the University of Michigan Health System and the second in 2016 with a policy focus at the University of Michigan. *Id.*

Dr. Callaghan is an Associate Professor of Neurology at the University of Michigan and a neuromuscular specialist with a primary interest in patients with neuropathy, such as cervical radiculopathy. Resp't's Ex. A at 1, ECF No. 51-1. Dr. Callaghan is certified by both the American Board of Psychiatry and Neurology and the American Board of Electrodiagnostic Medicine. *Id.*

Additionally, Dr. Callaghan has published more than 100 articles, focusing on "the appropriate diagnostic evaluation and treatment of peripheral neuropathy, such as cervical radiculopathy." *Id.* Dr. Callaghan estimated that he has seen more than 200 patients with cervical radiculopathy. *Id.*

ii. Expert Reports

1. Dr. Tornatore's Expert Report

Petitioner filed Dr. Tornatore's expert report on October 12, 2020. Pet'r's Ex. 53 at 1. Dr. Tornatore opined that Petitioner's Tdap vaccination on August 21, 2016 "resulted in significant aggravation of his underlying cervical degenerative disc disease[.]" *Id.* at 14.

Dr. Tornatore noted that Petitioner had only one pre-vaccination medical visit for cervical radiculopathy, in 2013, but had "multiple visits for ongoing symptoms of cervical pain with radicular symptoms in the left arm" post vaccination. *Id.* at 9. Specifically, Dr. Tornatore pointed to an EMG study five weeks post vaccination that showed "acute injury to the left C7 nerve root" and MRI imaging "consistent with degenerative disc disease at the C7 nerve root with encroachment upon the foramina through which the C7 nerve root exits." *Id.* at 10. Dr. Tornatore opined, in agreement with Petitioner's treating physicians, that "the underlying cause of [Petitioner's] arm and neck symptoms was acute structural compression of the C7 nerve root," reflecting "a significant aggravation of his underlying cervical radiculopathy that had been quiescent for 3 years." *Id.* Dr. Tornatore added that the significant aggravation occurred with "striking temporal association following the administration of a Tdap vaccination." *Id.* Dr. Tornatore summarized his conclusion by stating, "[i]t is my opinion that the vaccination did indeed result in significant aggravation of [Petitioner's] radiculopathy based on accepted and probable biological principles that occurred in a logical sequence of cause and effect in a striking temporal relationship, as reflected by the medical records in this case." *Id.*

Dr. Tornatore focused on two particular topics in this case: (1) the structural basis for cervical radiculopathy and (2) whether a Tdap vaccination can cause significant aggravation of a cervical radiculopathy, and if so, how. *Id.* For the first topic, Dr. Tornatore included various images showing the anatomy of the cervical spine. *Id.* at 11–13. Dr. Tornatore explained the following:

> Nerve roots [or radicles] exit the spinal cord through bony windows or neural foramina as they enter the neck and then progress down the arms. The neural foramina are formed by the junction of the pedicles[37] of adjacent vertebral bodies and the intervening intervertebral disc . . . the aging process results in bony protuberances or osteophytes[38] that encroach upon the neural foramina and potentially impinge on the nerve root. Likewise, degenerative changes in the intervertebral discs can cause further stenosis of the foramina.

[37] A pedicle is "a footlike, stemlike, or narrow basal part or structure, such as the stalk by which a nonsessile tumor is attached to normal tissue, or the narrow strip of flap tissue through which it receives its blood supply." *Dorland's* at 1380.

[38] An osteophyte is "a bony excrescence or osseous outgrowth." *Dorland's* at 1329.

Id. at 11. Dr. Tornatore opined that Petitioner had degenerative spine changes that placed him "at risk for developing acute radiculopathy." *Id.* This included one episode in 2013, followed by three years without symptoms. *Id.*

Dr. Tornatore continued that "the cervical vertebral bodies are surrounded by a large number of muscles[,]" which will "pull the vertebral bodies closer to one another causing further narrowing of the neural foramina and impingement of the nerve root" if the muscles spasm. *Id.* at 12. This impingement of a nerve root due to cervical spasm will "result in sensory symptoms, including pain, in characteristic dermatomal patterns[.]" *Id.* at 13. Dr. Tornatore opined that an impingement at C7, as Petitioner had, "can result in symptoms which start in the neck and extend down the arm." *Id.* Dr. Tornatore also noted "that the area which [Petitioner] received his Tdap vaccination was in the C7 dermatome[39] of the deltoid." *Id.*

Dr. Tornatore further opined that Petitioner's EMG study revealed "fibrillation potentials and positive waves, findings that are consistent with an acute injury." *Id.* (citing Pet'r's Ex. 55, ECF No. 47-4).[40] Dr. Tornatore added that "it takes between 1 and 4 weeks after a nerve injury before they can be identified." *Id.* Further, Dr. Tornatore opined that "the lack of polyphasic waves on [Petitioner's] EMG also speak[s] to an acute injury." *Id.* Dr. Tornatore added that "[Petitioner] had pre-existing bony pathology of the cervical spine which was made acutely worse following the [Tdap] vaccination as evidenced by his EMG study which was consistent with acute nerve root compression at the left C7 level." *Id.*

Next, Dr. Tornatore turned to the second topic, whether the Tdap vaccination could cause a significant aggravation of a cervical radiculopathy. *Id.* at 13. Dr. Tornatore cited to the "informational insert" for Adacel, one version of the Tdap vaccine. *Id.* (citing Pet'r's Ex. 56, ECF No. 47-5). The insert discussed a "Serious Adverse Event" ("SAE") report for "one diagnosis of nerve compression in neck and left arm" due to the vaccine. *Id.* (citing Pet'r's Ex. 56 at 11). The insert also reported that 65.7% of adults ages 18-64 experienced injection site pain and 21.9% of adults ages 18-64 experienced body ache or muscle weakness after vaccination. *Id.* (citing Pet'r's Ex. 56 at 2). Dr. Tornatore offered "a highly probably explanation" of "[Tdap]-induced cervical radiculopathy" that occurred in the above SAE: that "if a vaccination resulted in muscle spasm of the shoulder and cervical muscles in someone who already had underlying cervical disc disease and neural foraminal stenosis, cervical nerve roots would be compressed resulting in pain and sensory changes in dermatomal distribution." *Id.* at 14.

Further, Dr. Tornatore noted that the trapezius muscle is "[o]ne of the largest and most common muscles of the cervical spine that can result in cervical spasm[.]" *Id.* The trapezius "is in very close association with the deltoid, the muscle in which [Petitioner] received his vaccination." *Id.* Dr. Tornatore opined that "[a]ny pain in the deltoid can lead to spasm of the adjacent trapezius with resulting neck pain, a phenomena [Dr. Tornatore] has seen frequently in [his] practice over the past 3 decades." *Id.* Dr. Tornatore noted that Petitioner's "medical records had frequent references to deltoid pain at the site of vaccination, with associated trapezial spasm." *Id.*

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[39] The dermatome is "the area of skin supplied with afferent nerve fibers by a single spinal nerve." *Dorland's* at 491. Afferent nerve fibers are "nerve fibers that convey sensory impulses from the periphery to the central nervous system[.]" *Id.* at 1227.

[40] J. Feinberg, *EMG: Myths and Facts,* 2:1 Hospital for Special Surgery, 19–21 (2006).

2. Dr. Callaghan's Expert Report

Respondent filed Dr. Callaghan's expert report on February 19, 2021. Resp't's Ex. A at 1. Dr. Callaghan first noted that Petitioner received a diagnosis of "cervical disc disease causing a cervical radiculopathy" by multiple providers. *Id.* at 3. Then, Dr. Callaghan described cervical radiculopathy as a "common condition with an incidence of 83–179 per 100,000 person years"[41] with a typical causation of "compression of the nerve roots in the neck by arthritic changes and/or disc herniation[.]" *Id.* Dr. Callaghan added that while most cases "can be diagnosed based upon clinical history alone, [] MRI is the best imaging test to determine whether structural changes are consistent with a patient's symptoms[.]" *Id.* at 3–4.

Dr. Callaghan agreed with Dr. Tornatore that "left C7 cervical radiculopathy is the correct diagnosis[,]" but he disagreed that "the TDAP vaccination exacerbated [Petitioner's] pre-existing left C7 radiculopathy." *Id.* at 4. Next, Dr. Callaghan outlined four critiques of Dr. Tornatore's opinion that the Tdap vaccination significantly aggravated Petitioner's radiculopathy.

First, Dr. Callaghan responded to Dr. Tornatore's point regarding the single SAE involving nerve compression in neck and left arm in a clinical trial for Tdap vaccinations. *Id.* Dr. Callaghan opined that because there was only one case of nerve compression in the study, it is not statistically significant. *Id.* Further, Dr. Callaghan noted that "[r]are SAEs, such as this one, are useful to flag areas for future study, but they only suggest a proximal temporal relationship between TDAP vaccination nerve compression in the neck and left arm." *Id.* He explained that a "proximate temporal relationship alone is insufficient to show causation." *Id.* Dr. Callaghan also critiqued Dr. Tornatore's reliance on the SAE for a lack of details such that one cannot determine the patient's level of cervical radiculopathy. *Id.*

Second, Dr. Callaghan rebutted Dr. Tornatore's evaluation of the temporal association between the Tdap vaccination and Petitioner's cervical radiculopathy. *Id.* Instead, Dr. Callaghan noted that Petitioner had cervical radiculopathy for years, as documented by medical records in 2013 and a cervical x-ray. *Id.* (citing Pet'r's Ex. 53 at 9). Dr. Callaghan also stated that Petitioner did not mention the alleged post-vaccination symptoms to his neurologist at an appointment five days after the vaccination. *Id.*

Third, Dr. Callaghan discussed Dr. Tornatore's hypothesis "that muscle spasms will pull the vertebral bodies closer in the neck causing narrowing of the neuroforamin and that the vaccine caused [these] muscle spasm[s]." *Id.* Dr. Callaghan asserted that Dr. Tornatore provided no data or other scientific support for this claim. *Id.*

Fourth, Dr. Callaghan asserted that "there are no epidemiologic studies linking vaccinations in general, or TDAP specifically, with cervical radiculopathy, not even case reports."

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[41] Person years in a measurement used by scientists when performing certain types of prospective studies measured in time. *Verywell Health* (Jun. 6, 2024 at 11:26am), https://www.verywellhealth.com/person-years-and-person-months-3132812. "Person years and person months are types of measurement that take into account both the number of people in the study and the amount of time each person spends in the study. For example, a study that follows 1,000 people for one year would contain 1,000 person years of data. A study that follows 100 people for 10 years would also contain 1,000 person years of data." *Id.*

Id. Dr. Callaghan added that "there are no studies providing evidence of biologic plausibility or mechanisms linking TDAP vaccinations and cervical radiculopathy." *Id.*

Dr. Callaghan concluded by opining that "the cause of Petitioner's symptoms is more likely than not a left cervical C7 radiculopathy as diagnosed by multiple providers." Further, "[P]etitioner's cervical radiculopathy, as demonstrated by [his] MRI and EMG/NCS, was most likely caused by neuroforaminal narrowing from degenerative changes, and there is no evidence a vaccine can cause, or does cause, cervical radiculopathy." *Id.*

3. Dr. Tornatore's Supplemental Expert Report

Petitioner submitted a supplemental expert report from Dr. Tornatore on May 24, 2021. Pet'r's Ex. 58 at 1, ECF No. 55-2. Dr. Tornatore first reiterated the facts that both he and Dr. Callaghan agreed upon, including that Petitioner had a "prior history of a single episode of left cervical radiculopathy in 2013[,]" that there "were no documented visits to health care providers for this condition from 2013-2016[,]" that "there was an acute worsening of [Petitoner's] symptoms in August 2016[,]" that the "appropriate diagnosis in this case is left cervical radiculopathy[,]" and that the "EMG was consistent with an acute worsening of the cervical radiculopathy[.]" *Id.* at 1. Dr. Tornatore asserted that "there was no antecedent events other than the Tdap vaccination." *Id.* at 2. Next, Dr. Tornatore addressed two points of disagreement with Dr. Callaghan. *Id.*

First, Dr. Tornatore addressed the study discussed in the Adacel package insert involving an SAE of "one diagnosis of nerve compression in neck and left arm[,]" which the Principle Investigator ("PI") attributed to the vaccination. *Id.* Dr. Tornatore opined that this is a significant point because the event was labeled as an SAE, rather than the lower classification of "Adverse Event." *Id.* He explained that an SAE classification such as this one reflects a serious and deliberate calculation by the PI. *Id.* Next, Dr. Tornatore summarized the three prongs utilized to determine whether a study drug was the cause of an SAE: (1) "Is there a recognized biological mechanism?" (2) "Is the timing appropriate?" and (3) "Is there a reasonable sequence of cause and effect?" *Id.* Dr. Tornatore noted that these prongs require "extremely compelling" evidence that an SAE was caused by the study drug, which is why he believes that this reported SAE in a controlled clinical trial described as "vaccine-related radiculopathy" is significant. *Id.* Next, Dr. Tornatore replied to Dr. Callaghan's critique that one SAE is not statistically significant, instead asserting that rare SAEs cannot "rise to the level of statistical significance given that clinical trials are not powered to evaluate efficacy of a study, not rare events which would require enrolling millions of patients." *Id.* Dr. Tornatore opined that this vaccine related SAE is a persuasive significant rare event. *Id.*

Second, Dr. Tornatore addressed Dr. Callaghan's critique of his discussion of "the neural foramina and how it could be compromised following administration of a vaccine, particularly if muscle spasm caused narrowing of the neural foramina." *Id.* Dr. Tornatore stated that this "is an extremely common event in clinical neurology[,]" and in his three decades of practice, he has seen "thousands of cases of cervical radiculopathy with attendant muscle spasms resulting in reverse lordosis[42] of the cervical spine narrowing of the neural foramina." *Id.* To support this process, Dr. Tornatore cites an article, *Dropped Shoulder Syndrome: A Cause of Lower Cervical*

[42] Lordosis is "a dorsally concave portion of the vertebral column." *Dorland's* at 1060.

Radiculopathy, which stated, "[c]ompression of the cervical roots by muscle spasm has been proposed as the cause of dropped shoulder syndrome."[43] *Id.* at 2–3 (quoting Pet'r's Ex. 59 at 1, ECF No. 55-3). This article discussed dropped shoulder syndrome ("DSS"), a condition found in the Yemeni patients involved in this study. Pet'r's Ex. 59 at 2. DSS is the author's suggested name for this condition, which is characterized by the "small body build with visually detachable bilaterally dropped shoulders" occurring in "a considerable number of Yemeni people[.]" *Id.* Symptoms include "pain in one or both shoulders that radiates to the ipsilateral[44] upper limb, and other adjacent anatomical regions." *Id.* This article discussed a study on whether DSS is a cause of cervical radiculopathy. *Id.* The author found that "DSS is a major cause of lower cervical radiculopathy in Yemeni patients who present with shoulder pain, and had been investigated, with negative results, for other causes of shoulder pain." *Id.* at 5.

Additionally, Dr. Tornatore cited the Adacel vaccine package insert, which stated that "9.1% of adults who received the vaccine developed sore and swollen joints." Pet'r's Ex. 58 at 3 (citing Pet'r's Ex. 56 at 7). Dr. Tornatore continued that the "neural foramina borders the facet joint[,] which comes in close approximation to the neve root[,]" and if "there is any underlying facet disease, as was the case with [Petitioner], then any vaccine-induced swelling of this joint would further compromise the nerve root causing radicular pain." *Id.*

In conclusion, Dr. Tornatore stated that he "respectfully disagree[s]" with Dr. Callaghan's opinions. *Id.* Dr. Tornatore added that his "opinion still remains that the Tdap vaccination that [Petitioner] received on 8/21/206 resulted in significant aggravation of his underlying cervical degenerative disc disease[.]" *Id.*

4. Dr. Callaghan's Supplemental Expert Report

Respondent submitted Dr. Callaghan's supplemental expert report on August 9, 2021. Resp't's Ex. C at 1, ECF No. 56-1. To begin, Dr. Callaghan stated that Dr. Tornatore has not cited recognized biological mechanisms to explain Petitioner's condition. *Id.* Instead, Dr. Callaghan noted that Dr. Tornatore discussed "potential anatomic changes that he speculated may have occurred[,]" and Dr. Callaghan addressed these points in turn. *Id.*

First, Dr. Callaghan discussed Dr. Tornatore's opinion on the SAE in the clinical trial. *Id.; see also* Pet'r's Ex. 56 at 13. Dr. Callaghan argued that Dr. Tornatore failed to explain "how one SAE in one trial is supportive evidence for Tdap vaccination as a cause of cervical radiculopathy." Resp't's Ex. C at 1. Dr. Callaghan continued that while clinical trial SAEs are valuable tools to compare statistically significant adverse effects of different interventions and placebos, the cited study included only one case of "nerve compression in the neck and left arm" and lacked any statistical significance. *Id.* Dr. Callaghan also noted that the study lacked a placebo control group, instead only comparing the results of Tdap and tetanus-only vaccines. *Id.* Dr. Callaghan reiterated that the SAE showed only "a proximate temporal relationship between TDAP vaccination [and]

[43] Abdul-Latif, A., *Dropped Shoulder Syndrome: A Cause of Lower Cervical Radiculopathy*, Journal of Clinical Neurology, 2011 at 85–89.

[44] Ipsilateral means "situated on, pertaining to, or affecting the same side, as opposed to contralateral." *Dorlands* at 947.

nerve compression in the neck and left arm[,]" and "a proximate temporal relationship is insufficient to show causation." *Id.*

Next, Dr. Callaghan addressed the article submitted by Dr. Tornatore, titled *Dropped Shoulder Syndrome: A Cause of Lower Cervical Radiculopathy* by Ali A. Abdul-Latif. *Id.* at 2 (citing Pet'r's Ex. 59). Dr. Callaghan explained that this article described "dropped shoulder syndrome" which typically occurs in Yemen. *Id.* Dr. Callaghan continued that "[p]atients with this rare Yemeni disorder have slight body builds . . . and visibly detectable bilateral dropped shoulders" while Petitioner was obese and did not have dropped shoulders. *Id.* (citing Pet'r's Ex. 59 at 2; Pet'r's Ex. 3 at 6). The authors of the article proposed that the patients' cervical radiculopathy was potentially caused by muscle spasms triggered by the bilateral dropped shoulders. *Id.* (citing Pet'r's Ex. 59 at 1). The authors also noted that neck muscle traction or the abnormal posture common in this population may also be a potential cause of the cervical radiculopathy. *Id.* (citing Pet'r's Ex. 59 at 5). Dr. Callaghan cited three reasons why this article is not relevant to Petitioner's case: (1) Petitioner is not from Yemen, (2) Petitioner does not have "bilateral dropped shoulder syndrome or any comparable severe anatomical change that could lead to cervical radiculopathy[,]" and (3) Petitioner suffered from "known degenerative cervical changes and cervical radiculopathy prior to vaccination." *Id.*

Third, Dr. Callaghan addressed Dr. Tornatore's argument that "the vaccine induced swelling of the joints near the neuroforamen [] led to a cervical radiculopathy." *Id.* Dr. Callaghan asserted that Dr. Tornatore failed to provide any evidence to support this claim that vaccines, or Tdap in particular, can "lead to swelling in the joints near neuroforamina or that this swelling can be significant enough to cause a cervical radiculopathy." *Id.* Dr. Callaghan added that "this mechanism ignores the clear imaging changes before and after vaccination that reveal degenerative changes that are related to bone and disc changes in the neck and not joint swelling from a vaccination." *Id.*

III. Ruling on the Record

a. Petitioner's Motion

In Petitioner's motion for a ruling on the record, filed on December 12, 2022, Petitioner argued that he is entitled to compensation. Pet'r's Mot. at 30. Petitioner asserted that his preexisting cervical degenerative disk disease, which had been stable for three years prior, was significantly aggravated by his Tdap vaccination. *Id.* at 13. Specifically, Petitioner asserted that the significant aggravation took the form of "constant severe pain resulting in a muscle spasm of the shoulder and cervical muscles and consequent compression of the cervical nerve roots resulting in significant and prolonged pain and sensory changes." *Id.*

Petitioner relied upon the following agreed-upon facts as established by Petitioner's affidavit, medical records, and expert reporting: (1) Petitioner had preexisting cervical radiculopathy secondary to degenerative disk disease, which was diagnosed in 2013; (2) Petitioner's cervical radiculopathy did not recur after 2013 until the vaccination in 2016; and (3) the correct post vaccination diagnosis is C7 cervical radiculopathy, as stated by both Dr. Callaghan

and Dr. Tornatore. *Id.* at 14 (citing Pet'r's Ex. 42 at 10–11; Pet'r's Ex. 53 at 11–23; Resp't's Ex. A at 4).

Petitioner highlighted the qualifications of his expert, Dr. Tornatore, noting that he has been a board-certified neurologist since 1991, he serves as a Professor and Chairman of the Department of Neurology at Georgetown University Medical Center and Chairman and Neurologist-in-Chief at Medstar Georgetown University Hospital, and oversees an impressive amount of research in these roles. Pet'r's Mot. at 17–18. Petitioner argued that Dr. Tornatore is "highly regarded and highly respected in the field of neurology" and "qualified in every aspect of [Petitioner's] case[.]" *Id.* at 19. Petitioner pointed to Dr. Tornatore's medical theory outlined in his expert reports to support the significant aggravation of Petitioner's cervical radiculopathy. *Id.* 19–23.

Finally, Petitioner argued that he has met his burden under *Loving*, given the prior diagnosis, Petitioner's post-vaccination symptoms, and Dr. Tornatore's expert opinion on the matter. *Id.* at 29–30.

b. Respondent's Response

On January 9, 2023, Respondent filed a response to Petitioner's motion for a ruling on the record, arguing that Petitioner has not established that he is entitled to compensation. Resp't's Resp. at 2. [45]

Respondent asserted that Petitioner failed to establish a successful causation-in-fact SIRVA claim under *Althen*. *Id.* at 20. Respondent argued that Petitioner had a history of pre-vaccination left arm pain. *Id.* at 21 (citing Pet'r's Ex. 53 at 9–10). Further, Respondent criticized Dr. Tornatore's expert opinion for relying on a study based on Yemeni patients with "a rare Yemeni disorder with a different body hiatus than [P]etitioner and noticeably dropped bilateral shoulders, which [P]etitioner did not have." *Id.* at 21. Respondent asserted that Petitioner failed to satisfy *Althen* prongs one and two. *Id.* Respondent reasoned that Dr. Tornatore's opinion "is not based upon a reliable medical theory of casual connection or a logical cause and effect sequence" between the vaccination and injury because the Yemeni study is not reliable nor applicable to Petitioner. *Id.* Respondent further cited the fact that none of Petitioner's treating physicians attributed the aggravation of Petitioner's cervical radiculopathy to his vaccination. *Id.* at 24 (citing Pet'r's Ex 20 at 6; Pet'r's Ex. 23 at 14–16; Pet'r's Ex. 43 at 7, 9; Pet'r's Ex. 10 at 7, 9; Pet'r's Ex. 3 at 5–8). Respondent asserted that Petitioner also failed to meet *Althen* prong three because there is no objective evidence or medical basis that explains the timing between the vaccination and the onset of symptoms. *Id.* at 26 (citing Pet'r's Ex 20 at 6; Ex. 23 at 14–16; Pet'r's Ex. 43 at 7, 9; Pet'r's Ex. 10 at 7, 9; Pet'r's Ex. 3 at 5–8). Additionally, Respondent cited Petitioner's failure to report symptoms to his neurologist during an appointment five days post vaccination. *Id.* Respondent summarized Dr. Tornatore's analysis as a "*post hoc ergo propter hoc* rationale (*i.e.*,

[45] Respondent first argued that Petitioner failed to provide preponderant evidence of a SIRVA Table Injury. Resp't's Resp. at 15. It is unclear why Respondent addressed a SIRVA Table claim because Petitioner has never clearly plead a Table SIRVA claim. Petitioner's original petition included a causation-in-fact SIRVA claim. Pet. at 3. Petitioner's amended petition included a significant aggravation of cervical radiculopathy claim. Am. Pet. at 2.

the majority of petitioner's reported symptoms happened after his [Tdap] vaccination, so it likely must be because of the subject vaccine)." *Id.*

Lastly, Respondent argued that Petitioner did not establish significant aggravation of cervical radiculopathy under *Loving. Id.* at 27. Respondent asserted that Petitioner did not fulfill the *Loving* prongs because he failed to meet all three *Althen* prongs, which are incorporated in the *Loving* standard. *Id.* at 28.

c. Petitioner's Reply

In Petitioner's reply, filed on January 25, 2023, Petitioner clarified that he is seeking entitlement only for significant aggravation of cervical radiculopathy.[46] Pet'r's Reply at 1, ECF No. 63. Petitioner next disputed Respondent's analysis of Dr. Tornatore's report, asserting that Dr. Tornatore never "admit[ted] that there [was] insufficient information" within the Yemeni case study. *Id.* at 3. Further, Petitioner asserted that Dr. Tornatore's report included a comprehensive analysis of the SAE discussed in the vaccine insert, with application to Petitioner's case. *Id.* at 3–4. Petitioner also contested Respondent's assertion that Dr. Tornatore's expert report relied solely upon the above case studies. *Id.* at 4–5. Instead, Petitioner argued that the opinion was based upon Dr. Tornatore's expert opinion and "supported by sound and reliable medical and scientific evidence." *Id.* at 5.

Additionally, Petitioner rebutted Respondent's assertion that there is not a medically appropriate temporal relationship to satisfy *Althen* prong three and/or *Loving* prong six. *Id.* Petitioner relied on his affidavit, the opinions of treating physicians, and Dr. Tornatore's report to support an appropriate temporal relationship. *Id.* at 5–6 (citing Pet'r's Ex. 23 at 11; Pet'r's Ex. 43 at 7–9; Pet'r's Ex. 2 at 7; Pet'r's Ex. 4 at 4). Petitioner asserted that Respondent requiring treating physicians to "provide objective evidence or a medical basis that explained the temporal association" beyond opinion, diagnosis, and treatment itself, is requiring a higher burden than necessary. *Id.* Lastly, Petitioner noted that Respondent failed to address *Loving* prongs one through three, instead focusing only on *Althen*. *Id.* at 7.

IV. Applicable Legal Standard

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of a hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that the

[46] Petitioner stated that his petition does not include a Table SIRVA claim or a causation-in-fact shoulder injury claim. *Id.* at 1–2.

special master acted within his discretion in denying an evidentiary hearing); *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, he must prove that his injury was caused-in-fact or significantly aggravated by a Table vaccine.

In the seminal case of *Althen v. Sec'y of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). This may be accomplished in a number of ways. "Reliability and plausibility of . . . pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible." *See Pafford v. Sec'y of Health & Hum. Servs.,* No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380. The special master essentially must weigh and evaluate opposing evidence in deciding whether a petitioner has met their burden of proof. *See id.*; *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*,

569 F.3d at 1375–77. The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014). The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant,* 956 F.2d at 1148.

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). When and if a petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *de Bazan*, 539 F.3d at 1354; *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" § 300aa-13(a)(2).

In this case, Petitioner has alleged that his preexisting cervical radiculopathy was significantly aggravated by his vaccination. The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). In *Loving*, the United States Court of Federal Claims established the governing six-part test for off-Table significant aggravation claims. Petitioner must show by a preponderance of the evidence:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (adopting this as the proper legal standard for significant aggravation claims brought under the Vaccine Act).

The first two prongs of *Loving* are preliminary steps that are necessary to "evaluate the person's pre-vaccination condition and current, post-vaccination condition." *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996). Indeed, "these two steps are practically inherent in the term 'aggravation.'" *Id.* In *Sharpe*, the Federal Circuit clarified the *Loving* prongs and what is required by petitioners to successfully demonstrate a causation-in-fact significant aggravation claim. *Sharpe v. Sec'y of Health & Hum. Servs.,* 964 F.3d 1072 (Fed. Cir. 2020). *Loving* prong three requires only a comparison of a petitioner's current, post-vaccination condition, with her pre-existing, pre-vaccination condition. *Id.* at 1082; *Whitecotton*, 81 F.3d at 1099. A petitioner is not required to demonstrate an expected outcome or that her post-vaccination condition was worse than such an expected outcome. *Sharpe*, 964 F.3d at 1081. Further, a petitioner is not required "to disprove that a pre-existing genetic mutation caused [his] significant aggravation." *Id.* at 1087.

Loving prongs four, five, and six are derived from the three *Althen* prongs. *See Althen*, 418 F.3d at 1281. Under *Loving* prong four, a petitioner must provide a "medical theory causally connecting [the petitioner's] significantly worsened condition to the vaccination." *See Sharpe,* 964 F.3d at 1083; *see also Loving*, 86 Fed. Cl. at 144. In other words, a petitioner is required to present a medically reliable theory demonstrating that a vaccine "can cause a significant worsening" of the condition. *Sharpe*, 964 F.3d at 1083 (citing *Pafford*, 451 F.3d at1356–57). A petitioner may be able to establish a prima facie case under *Loving* prong four without eliminating a pre-existing condition as the cause of her significantly aggravated injury. *Id.* (citing *Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007) (noting that "the government bears the burden of establishing alterative causation . . . once petitioner has established a prima facie case")).

Loving prong five requires a petitioner to show "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." *Loving*, 86 Fed. Cl. at 144. In other words, a petitioner must show that the vaccination "did cause a worsening of [a petitioner's underlying disorder]." *Id.* The sixth prong of *Loving* is an adaptation of *Althen* prong three's requirement of a medically-acceptable temporal relationship. *Id.*

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.* There is no presumption that medical records are accurate and complete as to all the patient's physical conditions. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that "[b]ecause a reasonable fact finder could conclude that [the petitioner's] testimony [wa]s not inconsistent with her medical records . . . it was not arbitrary and capricious for the special master to credit [the

petitioner's] testimony" over her medical records). Where there are inconsistencies, special masters are within their discretion to award contemporaneous medical records greater weight than later conflicting testimony. *See Cucuras,* 993 F.2d at 1528 (holding that the special master's reliance on contemporaneous medical records over conflicting oral testimony given after the fact was not arbitrary or capricious); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master").

V. Analysis

a. Table Injury

Petitioner's pre-existing cervical radiculopathy precludes any potential Table SIRVA claim. *See* 42 CFR §100.3(c)(10). Further, as Petitioner pleaded in his amended petition and reiterated in his reply to Respondent's response to a motion for a ruling on the record, Petitioner is not claiming entitlement for a Table SIRVA. Am. Pet. at 2; Pet'r's Reply at 1–2. As such, I will not discuss the requirements for a Table SIRVA.

b. Pre-Vaccination Condition (*Loving* Prong One)

Both experts agree that Petitioner had a pre-vaccination diagnosis of cervical radiculopathy. Resp't's Ex. A at 1, 4; Pet'r's Ex. 53 at 9–10. Petitioner suffered from left upper arm pain and weakness with a reduced reflex, which Dr. McGee diagnosed as cervical radiculopathy on June 3, 2013. Pet'r's Ex. 43 at 10. Following his 2013 diagnosis and injection treatment, the medical records establish that Petitioner did not seek additional pre-vaccination treatment for his cervical radiculopathy or any condition involving neck pain or motor or sensory symptoms in his upper extremities. Petitioner did not address whether he experienced cervical radiculopathy symptoms pre-vaccination in his affidavit. There is preponderant evidence that Petitioner suffered from cervical radiculopathy prior to his vaccination at issue.

c. Current Condition/Post Vaccination Condition (*Loving* Prong Two)

The record establishes that after the vaccination, Petitioner's condition significantly worsened. Prior to the vaccination, Petitioner had not sought treatment for his cervical radiculopathy since 2013. Petitioner's affidavit provides evidence that he felt immediate pain after receiving the vaccination, which significantly worsened by the next morning. Pet'r's Ex. 40 ¶ 4. Throughout the following week, Petitioner's symptoms continued such that he could not work or rest. *Id.* ¶ 5. The first medical record noting Petitioner's post-vaccination symptoms is from September 8, 2016, eighteen days post-vaccination. Pet'r's Ex. 43 at 7. At this visit with Dr. McGee, Petitioner complained of "a reaction to [Tdap]" and left arm pain down to his hand. *Id.* Dr. McGee diagnosed Petitioner, again, with cervical radiculopathy with a note that it was a "[r]eaction to [Tdap]" and prescribed a pain medication and muscle relaxant. *Id.* at 9. Petitioner also sought out massage, steroid injections, increased pain medication, and chiropractic treatment within the first month and a half after the vaccination in an attempt to treat his symptoms. *See* Pet'r's Ex. 40 ¶ 6–17. Petitioner saw a number of physicians in various fields, including chiropractic, neurology, orthopedics, and physical therapy.

It is notable that Petitioner saw his neurologist, Dr. Hinton, on August 26, 2016, five days post vaccination and failed to mention any symptoms relating to the vaccination or his left arm pain. Pet'r's Ex. 23 at 14, 16. However, Dr. Hinton was treating Petitioner's sleep disorders, which resulted in a diagnosis of obstructive sleep apnea syndrome. *Id.* It is reasonable that Petitioner did not believe his arm pain was relevant to his neurology appointment. This is especially more significant considering that Petitioner still believed that his arm pain was routine post-vaccination soreness until August 28, 2017, according to his affidavit. *See* Pet'r's Ex. 40 ¶ 4.

The fact that Petitioner's cervical radiculopathy symptoms, which had not required treatment since 2013, escalated to the point that Petitioner sought out a multitude of various treatments post vaccination demonstrates that Petitioner's condition significantly worsened. This finding is further supported by Dr. McGee's diagnosis of cervical radiculopathy as a reaction to Tdap on September 8, 2016. *See* Pet'r's Ex. 43 at 7. As of the date he executed his affidavit, March 27, 2022, Petitioner reported that he has not found a successful treatment for his pain. *See* Pet'r's Ex. 40 ¶ 27. The fact that Petitioner failed to report arm pain during his neurology appointment five days post vaccination does not alter my finding that Petitioner experienced a significantly worsened condition after the vaccination.

d. Significant Aggravation (*Loving* Prong Three)

The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). A comparison of the findings of fact under the above *Loving* prongs shows that Petitioner's post-vaccination condition reflects a change for the worse from his pre-vaccination condition, including symptoms of numbness, tingling, and pain from his left arm, forearm, and hand, neck stiffness, and muscle spasms during the period following the vaccination. Dr. Callaghan and Dr. Tornatore agree that Petitioner's cervical radiculopathy worsened after the vaccination, with Dr. Callaghan only disputing that the vaccination caused this worsening of symptoms. Resp't's Ex. A at 4. The significant aggravation causation theory is addressed below by *Loving* prongs four through six.

e. General Causation (*Althen* Prong One/*Loving* Prong Four)

Petitioner is required to present a medical theory of causation demonstrating that the Tdap vaccine could have significantly aggravated Petitioner's preexisting cervical radiculopathy. Dr. Tornatore theorized that the vaccine injection resulted in muscle spasms of the shoulder and cervical muscles, which can trigger preexisting cervical radiculopathy by compressing the cervical nerve roots. Pet'r's Ex. 53 at 14. Dr. Tornatore elaborated that the deltoid muscle, the injection site, is closely associated with the trapezius muscle. *Id.* Any deltoid muscle pain can cause spasm of the trapezius with "resulting neck pain[.]" *Id.* Specifically, the "cervical nerve roots would be compressed[,] resulting in pain and sensory changes in a dermatomal distribution[,]" a phenomena that he has seen frequently in his practice over the past three decades. *Id.*

Dr. Tornatore did not explicitly characterize this injury as mechanical or inflammatory. Indeed, the medical theory that the injection triggered a muscle spasm, thus aggravating preexisting cervical radiculopathy, may be best characterized as a hybrid injury theory. The

mechanical injury can arise due to trauma from the improper insertion of the needle, while inflammation can result from the introduction of the vaccine into and around the outside of the deltoid. Dr. Tornatore's theory incorporates some aspects of the mechanical nature of SIRVA and describes a process where the injection triggers an inflammatory response.

Dr. Tornatore's theory provides preponderant evidence that the Tdap vaccination can cause a significant aggravation of preexisting cervical radiculopathy. Dr. Tornatore's opinion is supported by his testimony that he has regularly encountered this phenomenon in three decades of practice. The mechanical injury and resulting inflammation and symptoms are logical and sufficiently fleshed out under Dr. Tornatore's theory. Further, Dr. Callaghan criticized the cited data and medical literature, but failed to directly contest the theorized mechanism itself. The previous SIRVA cases in the Program support the legitimacy of a mechanical injury theory, paired with a resulting inflammatory process. Petitioner has met this prong.

f. Specific Causation (*Althen* Prong Two/*Loving* Prong Five)

As established above, Petitioner was diagnosed with cervical radiculopathy in 2013. Pet'r's Ex. 43 at 10–11, 16. The parties agree that Petitioner had not experienced cervical radiculopathy symptoms or sought further medical treatment for cervical radiculopathy since 2013. It is also undisputed that Petitioner sought treatment for an alleged reaction, including left arm pain which radiated to his hand, eighteen days after receiving the Tdap vaccination in 2016. *See* Pet'r's Ex. 43 at 7–9. However, the parties disagree as to whether the Tdap vaccination was the cause of Petitioner's symptoms.

Petitioner has presented preponderant evidence that the significant aggravation of his preexisting cervical radiculopathy manifested after vaccination. Petitioner's affidavit discussed the immediate onset of pain from the vaccination, which continuously became worse until he sought medical intervention with Dr. McGee eighteen days later. *See* Pet'r's Ex. 40 ¶¶ 5–10. Dr. McGee's diagnosis and treating plan included "[a]rm pain: Reaction to TDAP, [p]ossibly referred pain from neck, no induration" as well as preexisting cervical radiculopathy and lumbar disc disease. Pet'r's Ex. 43 at 9.

Petitioner sought timely medical intervention with a multitude of physicians and treatments. Petitioner consistently described his symptoms during these appointments, including left arm, neck, and shoulder pain and numbness, and attributed this pain to the 2016 Tdap vaccination. Pet'r's Ex. 43 at 7; Pet'r's Ex. 2 at 6–10; Pet'r's Ex. 4 at 4; Pet'r's Ex 23. at 11; Pet'r's Ex. 5 at 49; Pet'r's Ex. 3 at 5. Petitioner's treatments included muscle relaxers, neuropathic pain medications, opioid pain medications, anti-inflammatory medications, epidural treatments, massages, chiropractic treatments, and adjustments to his lifestyle. Petitioner's pain continues to affect him through at least the date of his affidavit. Pet'r's Ex. 40 ¶ 14.

The medical record contains preponderant evidence that but for the August 2016 Tdap vaccination, Petitioner would not have experienced a significant aggravation of his preexisting cervical radiculopathy. Petitioner's symptoms, diagnoses, including Dr. McGee's assessment that Petitioner experienced a reaction to the vaccination, and timeline are well documented in the medical record by treating physicians to sufficiently prove by a preponderance of the evidence that

the Tdap vaccination caused a significant aggravation of Petitioner's preexisting cervical radiculopathy. Petitioner satisfied prong two of *Althen*.

g. Proximate Temporal Relationship (*Althen* Prong Three/*Loving* Prong Six)

The final prong requires Petitioner to show that the timing of the injury fits with the causal theory. I find that there is preponderant evidence of an appropriate temporal relationship between Petitioner's Tdap vaccination and the significant aggravation of his cervical radiculopathy. Under Dr. Tornatore's mechanical muscle spasm theory, a patient would feel immediate pain with injection. Pet'r's Ex. 53 at 13. Petitioner's affidavit established that, at administration, "it hurt a lot more than other vaccines [Petitioner had] taken" and "REALLY hurt as [Petitioner] walked out of the store." Pet'r's Ex. 40 ¶ 3. Petitioner rested the remainder of the day because his arm was "so uncomfortable" and awoke the next day and his "left arm was extremely painful." *Id.* Petitioner also repeatedly recounted this timeline to his treating physicians, as is well-documented in the medical records.

Petitioner's immediate onset of pain with injection appropriately aligns with the medical theory. Further, there is no evidence that Petitioner was experiencing any left arm pain prior to his Tdap vaccination on August 21, 2016. Petitioner satisfied prong three of *Althen.*

VI. Conclusion

After careful review of the record, Petitioner has established by preponderant evidence that he suffered from a significant aggravation of his cervical radiculopathy as a result of his August 21, 2016 Tdap vaccination. Accordingly, Petitioner is entitled to compensation. This case shall proceed to damages.

IT IS SO ORDERED.

/s/ Herbrina D. Sanders
Herbrina D. Sanders
Special Master